K063797

510(k) SUMMARY

Submitter's name: Electrical Geodesics, Inc.
1600 Millrace Drive, Suite 307
Eugene, OR 97403

Contact name and address: Linda J. Bovard, Bovard Consulting LLC
29611 Simmons Road, Eugene, OR 97405
541-345-5431

JAN 25 2007

Date summary prepared: December 19, 2006

Device name:

Proprietary name:	Geodesic EEG System™ 300 (GES 300)
Common or usual name:	EEG system
Classification name:	Electroencephalograph, 84 GWQ Class II, 882.1400

Legally marketed device for substantial equivalence comparison:

Geodesic EEG System™ submitted by Electrical Geodesics, Inc. K012079

Description of the device:

The Geodesic EEG System™ 300 (GES 300) is a digital electroencephalograph system (EEG) with dedicated electrodes. It consists of an amplifier, computer, software, Geodesic Sensor Net® (electrodes), and additional components such as cables. Modifications which constitute the GES 300 include a compact amplifier, software upgrade, additional display modes and tools, and options for computer configuration.

Intended use of device:

The Geodesic EEG System™ 300 is intended to measure and record the electrical activity of the patient's brain. It can be used on adults, children, and infants.

Technological characteristics:

The modifications which constitute the GES 300 do not alter the technological characteristics of the device. These modifications have been controlled by the EGI Design Control procedures.

Testing conducted:

Verification and validation testing has been conducted and the GES 300 passed all structured testing.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Electrical Geodesics Incorporated
c/o Bovard Consulting LLC
Ms. Linda J. Bovard, RAC
29611 Simmons Road
Eugene, Oregon 97405

APR - 9 2012

Re: K063797
Trade/Device Name: Geodesic EEG System 300 (GES 300)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLT, GWQ
Dated (Date on orig SE ltr): December 19, 2006
Received (Date on orig SE ltr): December 29, 2006

Dear Ms. Bovard:

This letter corrects our substantially equivalent letter of January 25, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063797

Device Name: Geodesic EEG System™ 300 (GES 300)

Indications for Use:

- The Geodesic EEG System™ 300 (GES 300) is intended to measure and record the electrical activity of the patient's brain. It can be used on adults, children, and infants.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063797